K081590
p1/3

510K Summary

JUN 19 2008

1. SUBMITTER'S IDENTIFICATION

Ya Horng Electronic Co., Ltd.
James Kuo
No. 35, Zsha Lun, Jon Zsha Village, Antin Shiang, Tainan, Taiwan, R.O.C.
Tel : 886-6-593-2201
Fax : 886-6-593-0030
Email : jmkuo@yahorng.com

DATE PREPARED : May 28, 2007

2. DEVICE NAME

Trade Name : Ya Horng Arm Type Digital Blood Pressure Monitor
Model No. : BP-600, BP-600R, BP-600U, BP-600B, BP-600RB, BP-600UB ,BP-600J, BP-600RJ, BP-600UJ, BP-600BJ, BP-600RBJ, BP-600UBJ
Common/Usual Name : Blood Pressure Monitor
Classification Name : Non-invasive Blood Pressure Measurement System 21CFR 870.1130, DXN

3. PREDICATED DEVICE

It is substantially equivalent to the following device :
Microlife Intellectual Property GmbH, Model BP3AC1-1PC, FDA 510K, K060686, issued on June 9, 2006

4. DEVICE DESCRIPTION AND INTENDED USE

The Ya Horng Arm Type Digital Blood Pressure Monitors, Types BP-600, BP-600R, BP-600U, BP-600B, BP-600RB, BP-600UB , BP-600J, BP-600RJ, BP-600UJ, BP-600BJ, BP-600RBJ, BP-600UBJ are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by oscillometric method in which an inflatable cuff is wrapped around the upper arm. It uses an electronic capacitive pressure sensor to convert tiny alternations in cuff pressure to electrical signals. It analyze those signals to define the systolic and diastolic blood pressure and calculating pulse rate. Some models are with RS232 or USB ports to connect to the personal computer to store the measured data.

5. COMPARISON TO THE PREDICATE DEVICE-

Both models use the oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and the pulse rate. An upper arm cuff is inflated automatically; deflate rate is controlled by a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both models. Moreover, both models have PC link function, the memory function and auto power off function.

6. DISCUSSION OF NON-CLINICAL TESTS PERFORMED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE ARE AS FOLLOWS:

Following functional and performance testing were conducted to assess the safety and effectiveness of these Arm Digital Blood Pressure Monitor . All results are satisfactory.

a. **Reliability Test – Storage Test**
b. **Reliability Test – Operation Test**
c. **Reliability Test – Vibration Test**
d. **Reliability Test – Drop Test**

e. **Reliability Test – Life Test**
f. **EMC Test**

None of the tests demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazard.

7. DISCUSSION OF CLINICAL TESTS PERFORMED:

The clinical effectiveness conforms to the standard of ANSI/AAMI SP-10-2002.

8. CONCLUSION

When compared to the predicate device, the equipment does not incorporate any significant changes in the intended use, method of operation, material or design that could affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

Ya Horng Electronic Co., Ltd.
c/o Mr. Ned Devine
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
Northbrook, IL 60062

Re: K081590
Ya Horng Arm Type Digital Blood Pressure Monitor, Model Numbers BP-600, BP-600R, BP-600U, BP-600B, BP-600RB, BP-600UB, BP-600J, BP-600RJ, BP-600UJ, BP-600BJ, BP-600RBJ, BP-600UBJ.
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: May 29, 2008
Received: June 6, 2008

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081590

Device Name: Arm Type Digital Blood Pressure Monitor, Types BP-600, BP-600R, BP-600U, BP-600B, BP-600RB, BP-600UB, BP600J, BP-600RJ, BP-600UJ, BP-600BJ, BP-600RBJ, BP-600UBJ.

Indications for Use:

The Arm Type Digital Blood Pressure Monitor is a table top AC/DC powered operated arm type blood pressure monitor which is intended for use by adults for measuring the systolic and diastolic blood pressure and pulse rate. The measurement is by the oscillometric method wherein a cuff is placed on the upper arm and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced. The measurement result is shown on a LCD panel in the monitor. The measuring ranges are (1) blood pressure: 20 to 280 mmHg (2) pulse : 40 to 200 pulses/minutes.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081590